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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/333,251	06/15/1999	MICHAEL K. LANDI	26403.0075	3891

7590 02/01/2002

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EXAMINER

SMITH, RUTH S

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 02/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/333,251	LANDI ET AL.	
	Examiner Ruth S Smith	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 08 January 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-53 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-53 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims define the support structure with respect to the patient thereby including the patient as part of the claimed invention.

***Claim Rejections - 35 USC § 112***

Claims 31,32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 31 depends from claim 62, however, only claims 1-53 are pending.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1,3,7-11,13,16-18,21-22,26,29-30,33,51-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Brabrand. Brabrand discloses a system for

defining a direction of approach to a subsurface target. The system includes a support structure which carries a plurality of fiducials. These fiducials are any structure that can function as a reference such as the angle indicators. The fiducials define the approach path relative to the support structure. The system also includes a visible light source that travels along the predetermined path and is indicative of the direction of approach. The system also includes a reflector 46.

Claims 1,4,6-13,16-19,21-23,26,28-33,36-38,40,42,43,46-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Rapoport ('934). The claims are directly readable on Rapoport in that the markers are mounted in the skull of the patient which is in spaced relation to an external surface of the patient.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2,3,5,14,15,20,24,25,27,34,35,39,41,44,45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rapoport('934). Rapoport discloses the claimed invention including the use of either an MR imaging system or a CT imaging system in association with the guide system. Rapoport fails to disclose the use of radio-opaque or non-ferromagnetic fiducials or a reflector for directing the light beam. The use of radio-opaque or non-ferromagnetic fiducials or a reflector for directing the light beam are well known expedient in the art and therefore in the absence of any showing of unexpected results the use of such would have been matters of ordinary engineering design choice.

Claims 2,4-6,12,14,15,19,20,23-25,27,28,31,32,34,35 rejected under 35 U.S.C. 103(a) as being unpatentable over Brabrand. Brabrand discloses a system for

defining a direction of approach to a subsurface target. The system includes a support structure which carries a plurality of fiducials. These fiducials are any structure that can function as a reference such as the angle indicators. The fiducials define the approach path relative to the support structure. The system also includes a visible light source that travels along the predetermined path and is indicative of the direction of approach. The system also includes a reflector 46. Brabrand is silent with respect to the materials used for the support. The use of plastics and metals are old and well known in the medical arts and the selection of any of these would have been obvious to one skilled in the art. The selection of the known materials would inherently result in the use of materials having the claimed properties. In the absence of any showing of criticality, the specific shape of the support structure selected would have been an obvious design choice of known equivalents in the art. It is an old and well known expedient in the art to use a mirror to direct a light beam along a non-parallel axis rather than to direct it along a single axis. In the absence of any showing of unexpected results, whether one lined the light beam up directly with the entry point on the patient or lined it up off-axis and used a mirror to direct it to the entry point would have been a matter of ordinary engineering design choice.

### ***Response to Arguments***

Applicant's arguments filed January 8, 2002 have been fully considered but they are not persuasive. The skull is not considered to be an external surface of the patient. The layers of skin on top of the skull are considered to be an external surface of the patient. Therefore, when the markers are mounted in the skull they are in spaced relation to an external surface of the patient.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hussman discloses a system having optical means for indicating a path along which a medical device is to be inserted into a patient..

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Ruth S Smith  
Primary Examiner  
Art Unit 3737

RSS  
January 31, 2002